

**IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF ALABAMA
NORTHERN DIVISION**

EMBRY WAYNE HESTER as §
Personal Representative of the §
Estate of Martha Carolyn Hester, §
deceased, §

Plaintiff, §

vs. §

CASE NO.: 2:06-CV-242-MHT

MERCK & CO., INC. a New Jersey §
Corporation; et al., §

Defendants. §

ANSWER OF DEFENDANT MERCK & CO., INC.

COMES NOW, Defendant Merck & Co., Inc. (“Merck”), by and through its undersigned attorneys, and hereby answers the Complaint (“Complaint”) as follows:

Response to “Statement of the Parties”

1. Merck denies knowledge or information sufficient to form a belief as to the truth or falsity of the information contained in this paragraph of the Complaint.

2. Merck denies each and every allegation contained in this paragraph of the Complaint except that it admits it is a New Jersey corporation with its principal place of business in New Jersey and that it manufactured, marketed and distributed the

prescription medicine Vioxx® until Merck voluntarily withdrew Vioxx from the worldwide market on September 30, 2004.

3. Merck states that the allegations contained in this paragraph of the Complaint are not directed at Merck and therefore no response is required. Should a response be deemed required, Merck denies knowledge or information sufficient to form a belief as to the truth or falsity of the information contained in this paragraph of the Complaint.

4. Merck states that the allegations contained in this paragraph of the Complaint are not directed at Merck and therefore no response is required. Should a response be deemed required, Merck denies knowledge or information sufficient to form a belief as to the truth or falsity of the information contained in this paragraph of the Complaint.

5. Merck states that the allegations contained in this paragraph of the Complaint are not directed at Merck and therefore no response is required. Should a response be deemed required, Merck denies knowledge or information sufficient to form a belief as to the truth or falsity of the information contained in this paragraph of the Complaint.

6. Merck states that the allegations contained in this paragraph of the

Complaint are not directed at Merck and therefore no response is required. Should a response be deemed required, Merck denies knowledge or information sufficient to form a belief as to the truth or falsity of the information contained in this paragraph of the Complaint.

Response to “Factual Allegations”

7. Merck denies each and every allegation directed at Merck contained in this paragraph of the Complaint and avers that Merck sought and received the approval of the United States Food and Drug Administration (“FDA”) to manufacture and market the prescription medicine Vioxx and, until the voluntary withdrawal of Vioxx on September 30, 2004, did market Vioxx for the indicated uses set out in the relevant FDA approved prescribing information. Merck respectfully refers the Court to the FDA prescribing information for Vioxx’s indicated uses. Merck admits that Vioxx is a selective COX-2 inhibitor and that the mechanism of action of Vioxx is believed to be due to inhibition of prostaglandin synthesis via inhibition of an enzyme known as cyclooxygenase 2 (COX-2). Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in said paragraph.

8. Merck denies each and every allegation directed towards Merck contained in this paragraph of the Complaint except that it admits that it marketed and

distributed the prescription medicine Vioxx until Merck voluntarily withdrew Vioxx from the worldwide market on September 30, 2004. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in this paragraph of the Complaint.

9. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in this paragraph of the Complaint, and denies each and every allegation directed towards Merck contained in this paragraph of the Complaint, except admits that Merck marketed the prescription medication Vioxx, which was approved by the FDA as safe and effective for certain indicated uses in a manner consistent with the information contained in the relevant FDA-approved prescribing information, and respectfully refers the Court to the relevant FDA-approved prescribing information for Vioxx for its indicated uses and full text.

10. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in this paragraph of the Complaint, and denies each and every allegation directed toward Merck contained in this paragraph of the Complaint.

11. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in this paragraph of

the Complaint, and denies each and every allegation directed toward Merck contained in this paragraph of the Complaint.

12. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in this paragraph of the Complaint, and denies each and every allegation directed toward Merck contained in this paragraph of the Complaint.

13. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in this paragraph of the Complaint, and denies each and every allegation directed toward Merck contained in this paragraph of the Complaint.

14. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in this paragraph of the Complaint, and denies each and every allegation directed toward Merck contained in this paragraph of the Complaint.

15. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in this paragraph of the Complaint, and denies each and every allegation directed toward Merck contained in this paragraph of the Complaint.

Responses to Count I “Negligence”

16. Merck realleges, adopts and incorporates each prior averment as if set forth fully herein.

17. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in this paragraph of the Complaint, and denies each and every allegation directed toward Merck contained in this paragraph of the Complaint.

18. The allegations contained in this paragraph of the complaint are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation directed toward Merck in this paragraph of the Complaint. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in this paragraph of the Complaint.

19. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in this paragraph of the Complaint, and denies each and every allegation directed towards Merck contained in this paragraph of the Complaint, including subparts a-i.

20. Merck lacks knowledge or information sufficient to form a belief as to

the truth or falsity of the allegations not directed toward Merck in this paragraph of the Complaint, and denies each and every allegation directed towards Merck contained in this paragraph of the Complaint.

21. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in the first sentence of this paragraph of the Complaint, and denies each and every allegation directed towards Merck contained in the first sentence of this paragraph of the Complaint. The allegation contained in the second sentence of this paragraph of the complaint is a legal conclusion to which no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation directed toward Merck in the second sentence of this paragraph of the Complaint.

Response to Count II “Negligent Failure to Warn”

22. Merck realleges, adopts and incorporates each prior averment as if set forth fully herein.

23. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in this paragraph of the Complaint, and denies each and every allegation directed toward Merck contained in this paragraph of the Complaint.

24. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in this paragraph of the Complaint, and denies each and every allegation directed toward Merck contained in this paragraph of the Complaint.

25. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in this paragraph of the Complaint, and denies each and every allegation directed toward Merck contained in this paragraph of the Complaint.

26. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in this paragraph of the Complaint, and denies each and every allegation directed toward Merck contained in this paragraph of the Complaint.

Response to Count III “Misrepresentation and Suppression”

27. Merck realleges, adopts and incorporates each prior averment as if set forth fully herein.

28. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in this paragraph of the Complaint, and denies each and every allegation directed toward Merck

contained in this paragraph of the Complaint.

29. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in this paragraph of the Complaint, and denies each and every allegation directed toward Merck contained in this paragraph of the Complaint, including subparts a-e.

30. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in this paragraph of the Complaint, and denies each and every allegation directed toward Merck contained in this paragraph of the Complaint.

31. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in this paragraph of the Complaint, and denies each and every allegation directed toward Merck contained in this paragraph of the Complaint.

32. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in this paragraph of the Complaint, and denies each and every allegation directed toward Merck contained in this paragraph of the Complaint.

33. Merck lacks knowledge or information sufficient to form a belief as to

the truth or falsity of the allegations not directed toward Merck in this paragraph of the Complaint, and denies each and every allegation directed toward Merck contained in this paragraph of the Complaint.

34. The allegations contained in this paragraph of the complaint are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation directed toward Merck in this paragraph of the Complaint. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in this paragraph of the Complaint.

35. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in this paragraph of the Complaint, and denies each and every allegation directed toward Merck contained in this paragraph of the Complaint.

36. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in this paragraph of the Complaint, and denies each and every allegation directed toward Merck contained in this paragraph of the Complaint.

37. Merck lacks knowledge or information sufficient to form a belief as to

the truth or falsity of the allegations not directed toward Merck in this paragraph of the Complaint, and denies each and every allegation directed toward Merck contained in this paragraph of the Complaint.

Response to Count IV “Breach of Warranty”

38. Merck realleges, adopts and incorporates each prior averment as if set forth fully herein.

39. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in this paragraph of the Complaint, and denies each and every allegation directed toward Merck contained in this paragraph of the Complaint.

40. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in this paragraph of the Complaint, and denies each and every allegation directed toward Merck contained in this paragraph of the Complaint.

41. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in this paragraph of the Complaint, and denies each and every allegation directed toward Merck contained in this paragraph of the Complaint.

42. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in this paragraph of the Complaint, and denies each and every allegation directed toward Merck contained in this paragraph of the Complaint.

43. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in this paragraph of the Complaint, and denies each and every allegation directed toward Merck contained in this paragraph of the Complaint.

Response to Count V “Breach of Express Warranty”

44. Merck realleges, adopts and incorporates each prior averment as if set forth fully herein.

45. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in this paragraph of the Complaint, and denies each and every allegation directed toward Merck contained in this paragraph of the Complaint.

46. Merck lacks knowledge or information sufficient to form a belief as to

the truth or falsity of the allegations not directed toward Merck in this paragraph of the Complaint, and denies each and every allegation directed toward Merck contained in this paragraph of the Complaint.

47. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in this paragraph of the Complaint, and denies each and every allegation directed toward Merck contained in this paragraph of the Complaint.

Response to Count VI “Fraud”

48. Merck realleges, adopts and incorporates each prior averment as if set forth fully herein.

49. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in this paragraph of the Complaint, and denies each and every allegation directed toward Merck contained in this paragraph of the Complaint.

50. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in this paragraph of the Complaint, and denies each and every allegation directed toward Merck contained in this paragraph of the Complaint.

51. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in this paragraph of the Complaint, and denies each and every allegation directed toward Merck contained in this paragraph of the Complaint.

Response to Count VII

“Alabama Extended Manufacturer’s Liability Doctrine”

52. Merck realleges, adopts and incorporates each prior averment as if set forth fully herein.

53. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in this paragraph of the Complaint, and denies each and every allegation directed toward Merck contained in this paragraph of the Complaint, except admits that Merck manufactured, marketed and distributed Vioxx in a manner consistent with the relevant FDA-approved prescribing information until Merck voluntarily withdrew Vioxx from the worldwide market on September 30, 2004.

54. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in this paragraph of the Complaint, and denies each and every allegation directed toward Merck

contained in this paragraph of the Complaint.

55. For response to Plaintiffs' "Demand for Relief," Merck denies that Plaintiff sustained, or are entitled to, compensatory or punitive damages, or other recovery, fees, costs, expenses, or other relief.

**AS FOR A FIRST
DEFENSE, MERCK ALLEGES:**

Each and every claim asserted or raised in the Complaint is barred by the applicable statute of limitations and/or statute of repose, or is otherwise untimely.

**AS FOR A SECOND
DEFENSE, MERCK ALLEGES:**

The Complaint fails to state a claim upon which relief can be granted.

**AS FOR A THIRD
DEFENSE, MERCK ALLEGES:**

Each and every claim asserted or raised in the Complaint is barred by the doctrines of estoppel, res judicata, waiver, or statutory and regulatory compliance.

**AS FOR A FOURTH
DEFENSE, MERCK ALLEGES:**

If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries or losses were caused in whole or in part through the operation of nature or other intervening cause or causes.

**AS FOR A FIFTH
DEFENSE, MERCK ALLEGES:**

To the extent that Plaintiff asserts claims based on Merck's adherence to and compliance with applicable federal laws, regulations and rules, such claims are preempted by federal law under the Supremacy Clause of the United States Constitution.

**AS FOR A SIXTH
DEFENSE, MERCK ALLEGES:**

To the extent that Plaintiff asserts claims based upon an alleged failure by Merck to warn directly of alleged dangers associated with the use of Vioxx, such claims are barred under the learned intermediary doctrine because Merck has discharged its duty to warn in its warnings to the prescribing physician(s).

**AS FOR A SEVENTH
DEFENSE, MERCK ALLEGES:**

If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses were caused in whole or in part by the contributory negligence of the allegedly injured Plaintiff.

**AS FOR AN EIGHTH
DEFENSE, MERCK ALLEGES:**

If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses were only so sustained after Plaintiff's deceased knowingly, voluntarily, and willfully assumed the risk of any injury as the result of the

consumption of, administration of, or exposure to any drug or pharmaceutical preparation manufactured or distributed by Merck or other manufacturer.

**AS FOR A NINTH
DEFENSE, MERCK ALLEGES:**

If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Merck and over whom Merck had no control and for whom Merck may not be held accountable.

**AS FOR A TENTH
DEFENSE, MERCK ALLEGES:**

If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were proximately caused by Plaintiff's decedent's misuse or abuse of Vioxx.

**AS FOR AN ELEVENTH
DEFENSE, MERCK ALLEGES:**

If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses resulted from Plaintiff's decedent's pre-existing and unrelated medical, genetic and environmental conditions, diseases, or illnesses, subsequent medical conditions or natural courses of conditions for which this defendant is not responsible.

**AS FOR A TWELFTH
DEFENSE, MERCK ALLEGES:**

To the extent that Plaintiff relies upon any theory of breach of warranty, such claims are also barred for lack of timely notice of breach and lack of privity and because the alleged warranties were disclaimed.

**AS FOR A THIRTEENTH
DEFENSE, MERCK ALLEGES:**

Plaintiff's claims are barred, in whole or in part, under the applicable state law because Vioxx was subject to and received pre-market approval by the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

**AS FOR A FOURTEENTH
DEFENSE, MERCK ALLEGES:**

Plaintiff's claims are barred in whole or in part by the First Amendment.

**AS FOR A FIFTEENTH
DEFENSE, MERCK ALLEGES:**

Plaintiff's claims are barred, in whole or in part, because Plaintiff lacks capacity and standing to bring such claims, or is not the real party in interest.

**AS FOR A SIXTEENTH
DEFENSE, MERCK ALLEGES:**

Plaintiff's claims are barred in whole or in part because the product at issue was made in accordance with the state of the art at the time it was manufactured.

**AS FOR A SEVENTEENTH
DEFENSE, MERCK ALLEGES:**

To the extent that Plaintiff seeks punitive damages for an alleged act or omission of Merck, any award of punitive damages is barred under the relevant state law.

**AS FOR AN EIGHTEENTH
DEFENSE, MERCK ALLEGES:**

Plaintiff's claims are barred, in whole or in part, because Vioxx and its labeling was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

**AS FOR A NINETEETH
DEFENSE, MERCK ALLEGES:**

Plaintiff's claims are barred in whole or in part under comment k to Section 402A of the Restatement (Second) of Torts.

**AS FOR A TWENTIETH
DEFENSE, MERCK ALLEGES:**

Plaintiff's claims are barred in whole or in part because Merck provided legally adequate "directions or warnings" as to the use of Vioxx and any other drug or pharmaceutical preparation the Plaintiff alleges was taken within the meaning of comment j to Section 402A of the Restatement (Second) of Torts.

**AS FOR A TWENTY-FIRST
DEFENSE, MERCK ALLEGES:**

Plaintiffs' claims are barred under Section 4, *et. seq.*, of the Restatement (Third) of Torts: Products Liability.

**AS FOR A TWENTY-SECOND
DEFENSE, MERCK ALLEGES:**

Plaintiff's claims are barred in whole or in part because Vioxx "provides net benefits for a class of patients" within the meaning of comment f to Section 6 of the Restatement (Third) of Torts: Product Liability.

**AS FOR A TWENTY-THIRD
DEFENSE, MERCK ALLEGES:**

This case may be more appropriately brought in a different venue.

**AS FOR A TWENTY-FOURTH
DEFENSE, MERCK ALLEGES:**

Venue in this case is improper.

**AS FOR A TWENTY-FIFTH
DEFENSE, MERCK ALLEGES:**

Plaintiff's claims of fraud or misrepresentation are barred by reason of that Plaintiff's failure to allege the circumstances constituting fraud with particularity, as required by Federal Rule of Civil Procedure 9(b).

**AS FOR A TWENTY-SIXTH
DEFENSE, MERCK ALLEGES:**

To the extent Plaintiff has settled or will in the future settle with any person

or entity with respect to the injuries asserted in the Complaint, Merck's liability, if any, should be reduced accordingly.

**AS FOR A TWENTY-SEVENTH
DEFENSE, MERCK ALLEGES:**

To the extent Plaintiff seeks recovery for benefits entitled to be received or actually received from any other source for injuries alleged in the Complaint, such benefits are not recoverable in this action.

**AS FOR A TWENTY-EIGHTH
DEFENSE, MERCK ALLEGES:**

To the extent that Plaintiff seeks punitive damages for the conduct which allegedly caused injuries asserted in the Complaint, such an award would also, if granted, violate Merck's state and federal constitutional rights.

**AS FOR A TWENTY-NINTH
DEFENSE, MERCK ALLEGES**

Plaintiff's claims are barred in whole or in part because that Plaintiff has failed to mitigate the alleged damages.

**AS FOR A THIRTIETH
DEFENSE, MERCK ALLEGES:**

To the extent Plaintiff claims punitive damages, Merck asserts that Plaintiff has not complied with statutory requirements to recover punitive damages.

**AS FOR A THIRTY-FIRST
DEFENSE, MERCK ALLEGES:**

To the extent Plaintiff's claims invoke punitive damages, such claims violate the Fourth, Fifth, Sixth, Eighth and Fourteenth Amendments of the Constitution of the United States, on the following grounds:

- (a) It is a violation of the Due Process and Equal Protection Clauses of the Fourteenth Amendment of the United States Constitution to impose punitive damages, which are penal in nature, against a civil Defendant upon a Plaintiff satisfying a burden of proof which is less than the "beyond a reasonable doubt" burden of proof required in criminal cases;
- (b) The procedures pursuant to which punitive damages are awarded may result in the award of joint and several judgments against multiple Defendants for different alleged acts of wrongdoing, which infringes the Due Process and Equal Protection Clauses of the Fourteenth Amendment of the United States Constitution;
- (c) The procedures pursuant to which punitive damages are awarded fail to provide a reasonable limit on the amount of the award against Defendant, which thereby violates the Due Process Clause of the Fourteenth Amendment of the United States Constitution. *See Pacific Mut. Life Ins. Co. v. Haslip*, 111 S. Ct. 1032, 113 L. Ed. 2d 1.
- (d) The procedures pursuant to which punitive damages are awarded fail to provide specific standards for the amount of the award of punitive damages which thereby violates the Due Process Clause of the Fourteenth Amendment of the United States Constitution;
- (e) The procedures pursuant to which punitive damages are awarded result in the imposition of different penalties for the same or similar acts and, thus, violate the Equal Protection

Clause of the Fourteenth Amendment of the United States Constitution;

- (f) The procedures pursuant to which punitive damages are awarded permit the imposition of punitive damages in excess of the maximum criminal fine for the same or similar conduct, which thereby infringes the Due Process Clause of the Fifth and Fourteenth Amendments and the Equal Protection Clause of the Fourteenth Amendment of the United States Constitution; and,
- (g) The Retroactive application of punitive damages violates the contracts clause of the United States Constitution, Article I, Section 10.
- (h) Plaintiffs' claims for punitive damages violate the due process clause of Article I, Section 13 of the Constitution of Alabama, on the following grounds:
 - (1) It is a violation of the due process clause to impose punitive damages which are penal in nature, upon a civil Defendant upon a Plaintiff satisfying a burden of proof less than the "beyond a reasonable doubt" burden of proof required in criminal cases;
 - (2) The procedures pursuant to which punitive damages are awarded fail to provide a limit on the amount of the award against these defendants;
 - (3) The procedures pursuant to which punitive damages are awarded are unconstitutionally vague;
 - (4) The procedures pursuant to which punitive damages are awarded fail to provide specific standards for the amount of the award of punitive damages; and,
 - (5) The award of the punitive damages in this case constituted a deprivation of property without due process of law.

- (i) Plaintiffs' attempt to impose punitive or extra-contractual damages on this defendant, on the basis of vicarious liability for the conduct of others, violates the Fifth and Fourteenth Amendments of the United States Constitution.
- (j) The award of punitive damages to any of the Plaintiffs in this action would constitute a deprivation of property without due process of law required under the Fifth and Fourteenth Amendments of the United States Constitution.
- (k) The procedures pursuant to which punitive damages are awarded permit the imposition of an excessive fine in violation of Article I, Section 15, of the Constitution of Alabama.
- (l) The award of punitive damages against these defendants in this action would violate the prohibition against laws that impair the obligations of contracts in violation of Article I, Section 22 of the Constitution of Alabama.
- (m) The procedures pursuant to which punitive damages are awarded are vague and unpredictable such that they violate the defendant's right to defend himself pursuant to Article I, Section 10 of the Constitution of Alabama.
- (n) The procedures pursuant to which punitive damages are awarded permit the imposition of punitive damages in excess of the amount established by the legislature under Ala. Code, Section 27-1-17 (1975), in violation of the Due Process Clause of the Fifth and Fourteenth Amendments of the U. S. Constitution and Article, Section 6, of the Alabama Constitution.

**AS FOR A THIRTY-SECOND
DEFENSE, MERCK ALLEGES:**

The Complaint seeks to make Merck liable for punitive damages. The United States Supreme Court has reversed the Alabama Supreme Court in the case

styled *BMW of North America, Inc. v. Gore*, 116 S.Ct. 1589 (1996) on the issue of punitive damages. Merck adopts by reference the defenses, criteria, limitations, and standards mandated by the United States Supreme Court decision in that case and in *Cooper Industries, Inc. v. Leatherman Tool Group, Inc.*, 532 U.S. 424 (2001), *State Farm Mutual Automobile Insurance Co. v. Campbell*, 538 U.S. 408 (2003), and any subsequent applicable decisions.

**AS FOR A THIRTY-THIRD
DEFENSE, MERCK ALLEGES:**

Merck affirmatively pleads that any punitive damages that the Plaintiff may recover in this case should be capped in keeping with Alabama Code Section 6-11-21, as amended in 1999 (Act. No. 99-358) and in the spirit of the Alabama Supreme Court's decision in *Oliver v. Towns*, 738 So. 2d 798 (Ala. 1999).

**AS FOR A THIRTY-FOURTH
DEFENSE, MERCK ALLEGES:**

The demand for punitive damages in the instant case is subject to the limitations established by the Alabama legislature and set forth in Ala. Code §6-11-21, (1975). Merck adopts by reference the defenses, criteria, limitations, and standards mandated by this Alabama statute. The Alabama Supreme Court's action in abolishing the legislatively created cap on punitive damages was unconstitutional and is without effect. Under the Constitutions of the United States

and the State of Alabama, the Alabama Supreme Court cannot abolish the cap created by the legislature on punitive damages through this judicial decision. *See Honda Motor Company, Ltd. v. Oberg*, 512 U.S. 415, 114 S. Ct. 2331, 2340 n.9 (1994).

**AS FOR A THIRTY-FIFTH
DEFENSE, MERCK ALLEGES:**

Merck avers that the punitive damage cap set out in *Ala. Code* §6-11-21, (1975) applies to the instant case. *See Horton Homes, Inc. v. Brooks*, 832 So. 2d 44 (Ala. 2001).

**AS FOR A THIRTY-SIXTH
DEFENSE, MERCK ALLEGES:**

Merck avers that the punitive damages award is subject to limitation based on harm that has occurred and harm that is likely to occur. *See TXO Production Corp. v. Alliance Resources Corp.* 113 S. Ct. 2711 (U.S. 1993).

**AS FOR A THIRTY-SEVENTH
DEFENSE, MERCK ALLEGES:**

Merck avers that the method of imposing punitive damages violates Amendment 328, Section 6.11, which prohibits the use of a procedural rule to abridge, enlarge or modify the substantive right of any party. *See Leonard v. Terminix Intern. Co., L.P.* 854 So. 2d 529 (Ala. 2002).

**AS FOR A THIRTY-EIGHTH
DEFENSE, MERCK ALLEGES:**

The imposition of punitive damages is an act of policy making on the part of the judiciary, in violation of Article III, Section 43 of the Constitution of Alabama.

**AS FOR A THIRTY-NINTH
DEFENSE, MERCK ALLEGES:**

Merck adopts the terms of any applicable legislative act or Alabama Supreme Court decision which now or hereafter precludes punitive damages or limits the amount of punitive damages that can be recovered in an action at law in Alabama.

**AS FOR A FORTIETH
DEFENSE, MERCK ALLEGES:**

Plaintiff's joinder of these Defendants in one action is improper under the applicable Rules of Civil Procedure and is not consistent with the interests of judicial economy.

**AS FOR A FORTY-FIRST
DEFENSE, MERCK ALLEGES:**

Merck adopts and incorporates by reference all defenses interposed by other Defendants except to the extent that they are inconsistent with Merck's pleading in this Answer.

Inasmuch as the Complaint does not describe the alleged underlying claims with sufficient particularity to enable Merck to determine all of its legal, contractual and equitable rights, Merck reserves the right to amend and supplement the averments of its answer to assert any and all pertinent liability defenses ascertained through further investigation and discovery of this action. Merck will further rely on all defenses that are included in the master Answer filed in the Multi-District Litigation proceedings before Judge Fallon of the Eastern District of Louisiana (the “MDL”), that may become available during discovery in this case or in the MDL or in the trial of this case.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiffs’ claims with prejudice and awarding Merck its reasonable costs and disbursements, together with such and other and further relief that the Court may deem just and proper.

JURY DEMAND

Merck demands a trial by jury as to all issues so triable.

/s/ Benjamin C. Wilson
One of the Attorneys for Defendant
Merck & Co., Inc.

OF COUNSEL:

Robert C. "Mike" Brock (ASB-5280-B61R)
F. Chadwick Morriss (ASB-8504-S75F)
Benjamin C. Wilson (ASB-1649-I54B)
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CERTIFICATE OF SERVICE

I hereby certify that on April 12, 2006, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the following:

Tom Dutton
Elisabeth French
Pittman, Hooks, Dutton, Kirby & Hellums, P.C.
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/s/ Benjamin C. Wilson